NRC NEWS

U.S. NUCLEAR REGULATORY COMMISSION

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No. S-04-005

Special Session of the 37th JAIF Annual Conference

Status and Future Outlook for
Regulation of Nuclear Power Plants in the US

(a Regulatory Program for the 21th Century)

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April 21, 2004
Tokyo, Japan

Introduction

Good morning. It is indeed an honor to address the Japan Atomic Industrial Forum and a real personal pleasure to share with this distinguished group my views on a nuclear power plant regulatory program for the first quarter of this century; for today and possibly the next 25 years. The ideas and activities that I will be discussing have been developed in the context of the U.S. nuclear reactor program. The regulators and the nuclear industry in Japan and elsewhere must decide if these are useful for their country. Today, I will expand on some thoughts I presented at the 2004 U.S. - Japan, Nuclear Energy Workshop on the subject of "The Role of Nuclear Regulation in a Changing World."

The regulation of nuclear power plants in the U.S. has an established and functional foundation, yet it is in a transitional phase. Building on the traditions, approaches, and decisions of the past, we are developing, testing, and using state-of-the-art safety methods and technologies, including a risk-informed and performance-based regulatory approach to safety that is realistic and conservative, to implement a regulatory program for now and the near future. The existing regulatory fabric, woven piece-by-piece, and stitched together during the 1960's, 70's, 80's and 90's, has served us well; but that patch work is not efficient for existing plants and definitely not sufficient or effective enough for a new generation of nuclear power plants. We need, and we are constructing, a regulatory program that better meets our present needs, one that will be maintained in-phase with the technological developments of the 21th century. It is worthwhile to note that these regulatory improvements are, in many ways, enabled by a nuclear power industry that has been improving safety and reliability performance for many years.

The NRC, amid a changing world scenario, is continuing strong oversight of the 104 operating reactors in the U.S., and our review of applications for license renewal, power up-rate, and other licensing changes is effective and efficient. Furthermore, standard design certification work is ongoing and we have begun our oversight of new areas, including Early Site Permits and Combined Operating Licenses. New reactor design and pre-application work is also being conducted. The new regulatory fabric is being woven, in a systematic, disciplined and open manner. This new regulatory fabric requires the seamless weaving or inter-weaving of numerous safety issues, as well as their integration with associated technical considerations. Some of them are new and some are old, and most have been seen and addressed as separated and isolated issues in the past.

The U.S. NRC regulatory framework is more risk-informed and becoming more performance-based. It increasingly relies on Probabilistic Safety Assessments to make sound regulatory decisions. Probabilistic Safety Assessment has been recently woven together with traditional, defense-in-depth engineering approaches and with performance monitoring techniques to establish risk-informed and performance-based regulation. Reactor safety, physical security and emergency preparedness are being woven together into a single broader concept of safety. Realism and conservatism are being woven into realistic conservatism. The oversight of operation, maintenance, design and other aspects of nuclear power plant safety are being woven into a safety management program (some call it safety culture, but I still prefer safety management). And now we can see the need to connect them, and the possibility of unifying them. I believe it is both possible and necessary to combine these regulatory modules into a single architecture where the interactive determinants and outcomes of safety/security/emergency preparedness areas are understood, and managed through a risk-informed and performance-based approach supported by realistically conservative analyses. The driver and overall outcome is the reasonable assurance of adequate protection of public health and safety, the environment and the common defense and security. Allow me to take a few minutes to address the importance of improving the regulatory process in general and some of the areas of improvement in more detail.

The Proper Role of Regulation

I believe the outlook for nuclear energy is very good, if we consider the improved state of the technology, the assured supplies of fuel, the expectations of the world for an improved quality of life and for socio-political stability, and when appropriate and effective regulatory programs are available to provide reasonable assurance of safety and protection of the environment. We still need to communicate all of the above better, but that is another topic in itself.

The viability, and the probable growth, of nuclear power is inextricably linked to its regulation. I want to be crystal clear in addressing this issue. There is no way, presently and in the foreseeable future, to maintain and to advance the use of nuclear power in a free society without a strong, predictable and credible regulator. Therefore, it is essential that regulatory infrastructures be all that they can be: safety-focused, with state-of-the-art know-how in every important safety aspect. As regulators we make independent decisions, listening to and respecting different views, but without undue interference. We at the NRC should be willing to risk criticism by communicating both the good and the not-so-good safety performance, as well as assessing and explaining potential risks with realistically conservative analysis, always based on providing assurance of protection of the public.

For example, we recognized our shortcomings related to the Three Mile Island accident 25 years ago, and we recognized what should have been done better with the Davis-Besse vessel head degradation. We should be good at identifying our deficiencies; we should also be good at learning from them.

Regulation is a tool of society to achieve predictable and beneficial use of an activity. I have said many times: “Regulation must result in a benefit or it will result in a loss.” I dare to say this is particularly true in the case of nuclear power, a technology that is always in the public eye and subjected to public perception, in a still unforgiving environment regarding its performance.

Good regulation provides for the proper exercise of democratic and free-market processes to enhance the common good. It is established to provide a framework that allows for the conduct of individual, industrial, commercial, financial, and other activities. Although regulations restrict, regulation should not deter beneficial activities, but frame them and guide them. Thus, the minimal amount of regulation that achieves the primary objective is best for our society.

Poor regulation, on the other hand, provides too few or too many controls, focusing more on restricting, limiting, and controlling, losing sight of the common good. This is in direct contradiction to the fundamentals of a democratic society and the free market. Poor regulation can create the illusion of being "protective" while stripping freedom, all the way to the individual.

It is frequently too easy to do a little more "regulation," to appear a bit more "protective," and to add another ounce of "conservatism." More regulation can appear enticing. I am convinced that the right goal should be to have less but better regulation. I believe this to be true because we have powerful self-correcting forces that will act promptly in favor of the people. These self-correcting forces are inherent to democracy itself, and include a free market system and the free flow of information.

And that brings us to our regulatory standard: reasonable assurance of adequate protection of public health and safety. The NRC is not in the business of zero risk. We are responsible for assuring that the risk is understood, that it is managed, and that it is acceptably low. Zero is not an option, it is a disruption. Today, with risk-informed regulatory tools, we know how to mix and match deterministic and probabilistic regulation, how to add requirements and how to decrease the unnecessary ones -- and we have the will to do it. We are learning how to define adequate protection in more precise terms, and to define it in terms that make sense to the American people. In other words, we are quantifying safety and communicating it better.

Directly connected to all of the above is the pressing need to bring state-of-the-art know-how to nuclear radiation technology and energy production, and to develop even newer and better techniques, applications and processes. With this, there is also a need for better, more functional and more realistic safety considerations; and, of course, with them the enabling regulation.

Risk-Informed and -Performance-Based Regulation

This is a year of anniversaries, 50 years of Atoms for Peace; 25 years from Three Mile Island; and even 30 years from the Wash-1400 "Reactor Safety Study," which introduced Probabilistic Risk Assessment, or PRA, as a tool to improve reactor safety analysis. Wash-1400 gained prominence with the Three Mile Island accident. Following the accident, the NRC undertook a careful and retrospective analysis of its regulations and regulatory practices in the "NRC Special Inquiry." In that report, a number of recommendations call for the increased use of risk analysis and risk insights. These recommendations include the following:

> "The best way to improve the existing design review process is by relying in a major way upon quantitative risk analysis" and added,
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> "What we [the NRC Special Inquiry] are suggesting is that [the existing review process] be augmented and that quantitative methods be used as the best available guide to which accidents are the important ones, and which approaches are the best for reducing their probability and consequences," and again, it included a recommendation,
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> "We strongly urge that NRC begin the long and perhaps painful process of converting as much as is feasible of the present review process to a more accident-sequence-oriented approach."

I agree with most of their recommendations, and agree with their statement that the transition to an accident-sequence-oriented approach would be "long" and "painful." It should not have been that long or that painful to achieve a risk-informed regulatory structure, but it has been. The wheels of nuclear regulatory progress turn slowly, but they are accelerating.

In 1995, nearly nine years ago, the Commission issued a formal Commission Policy Statement supporting the increased use of PRA in a manner that was well integrated with engineering approaches, including defense-in-depth, and with operational safety experiences. This integration defines risk-informed regulation. We have made significant progress in the use of PRA since 1995, but we are far from done. Further progress has been achieved by combining the concept of risk-informed regulation, where appropriate, with a performance-based approach to produce the framework of risk-informed and performance-based regulation. A performance-based regulatory approach achieves defined objectives and focuses on results. It differs significantly from a prescriptive approach in which licensees are provided detailed direction on how those results are to be obtained. It has been a long road; but that's our history and we cannot change it. We do have the opportunity to change the future, and I submit to you that we have the obligation to do so.

Two major steps on the road to a risk-informed and performance-based regulatory framework are close at hand, and they are important, practically and philosophically. I am talking about 10 CFR 50.69 and 50.46. The technical information and analytical methods are available and the will to

change is strong. Risk-informed decision-making is an everyday tool for the nuclear industry and the NRC. Risk and risk configuration management is calculated every day and used in operational safety decisions. Why not in the basic design requirements too? We have a sufficient understanding of the probabilities and consequences to be able to progress to the next rational level of regulation to improve reactor safety.

For the emergency core cooling system and LOCA proposed rule, I am convinced that, as a matter of improving safety, the consideration of very low probability Large-Break LOCAs should be addressed as severe accident scenarios, in a severe accident management program, rather than as the design basis accident. Effectively, the current Large-Break LOCA would not be a design basis accident when utilizing a risk-informed approach. With this alternative approach, the really important, risk-significant accident scenarios would remain within the design basis; in fact, their consideration would be enhanced by a new focus on their risk-importance. The commitment to go forward with 50.46 is fully formed and the NRC staff will develop proposed rule changes and associated guidance for public review and comment over the next several months. In addition, we expect one or more pilot applications which would request risk-informed changes to the Large-Break LOCA requirements through the NRC exemption process. This will provide a way of getting direct and practical experience with some of the important decisions to be made. We have found this approach very useful in the past. The re-definition of the Design Basis LOCA is just one step, but a very important step, in the effort to revise the regulatory requirements to be more risk-informed and more broadly coherent.

Integration of Safety/Security/Emergency Preparedness

I mentioned reactor safety, physical security and emergency preparedness earlier. I see these areas as a tightly connected triad -- three intertwined areas, in which the programs, and their regulatory requirements work in an integrated, synergistic way to protect public health and safety. In fact, it is the holistic, functional combination of reactor safety, physical security, and emergency preparedness that provides the basis for assuring public safety.

The relationship among these three areas can be understood by looking at their contributions to overall protection provided through defense-in-depth. The concept of defense-in-depth is a centerpiece of our approach to ensuring adequate protection of public health and safety. Defense-in-depth calls for, among other things, high quality design, fabrication, construction, inspection, and testing; multiple barriers to fission product release; redundancy and diversity in safety equipment; and procedures and strategies to address the expected as well as the unexpected. It must incorporate the dynamics of risk-informed and performance-based decision making. Or better: use risk-informed and performance-based regulation to add realism to defense-in-depth conservatism.

I want to share with you my thoughts on the interrelationships among reactor safety, physical security, and emergency preparedness and their importance to our present focus on mitigation of potential terrorist threats. For example, security concerns, including terrorist threats, raise many of the same issues involved in avoiding and mitigating reactor accidents. Potential initiating events, safety functions, safety (and often non-safety) equipment and procedures, and design basis and severe accident management guidelines all converge to a simple postulate: shut down the reactor, cool the core, and maintain barrier integrity. These are things we know how to do well and should be able to do regardless of the initiating event.

Likewise, it is clear that such system requirements as redundant emergency core cooling systems, redundant and diverse heat removal systems, fire protection features (including separation and suppression systems), and station blackout capabilities (either additional AC power sources or coping capability without AC power) provide built-in means of dealing with attempted attacks on nuclear reactors. And lastly, the emergency procedures and severe accident management strategies developed for reactor accidents also provide means for mitigating the potential consequences of terrorist attacks should they occur. The U.S. nuclear industry has utilized emergency procedures and severe accident management strategies to implement enhancements required by the NRC's security orders of February 25, 2002, because these procedures and strategies are so well suited to be effective against a broad range of events involving possible terrorist activities.

With regard to emergencies, both on-site and off-site mitigating measures will be taken. When the defense-in-depth procedures and strategies are used on-site, they are generally considered part of the reactor safety approach; when they go beyond the plant boundaries, they are generally considered part of "Emergency Preparedness." In treating emergency preparedness as another level of defense-in-depth, we are recognizing it as an integral part of our approach to protecting the public. Reactor fuel, reactor coolant systems, containment, emergency preparedness -- these are four barriers, each one complementing the others, and each one designed, tested, and inspected to provide a reasonable assurance of protecting the public and the environment from radiological releases.

Realistic Conservatism

I have used the term realistic conservatism a few times; let me explain what I mean. I am convinced nuclear regulation now needs to be anchored in realistic conservatism (or conservative realism), and especially so if we are to avoid the twin pitfalls of under-regulation and over-regulation. I see realism and conservatism as enabling factors for safety and reliability.

For purposes of simplicity, I use "conservatism" in the sense of preserving adequate safety margins, and I use "realistic" in the sense of being anchored in the real world of physics, technology and experience. Let me now turn to what I mean by "realistic conservatism": it combines the essence of the above-mentioned definitions, and uses prudence and hard-headed common sense, firmly grounded in real-world conditions, coupled to a commitment to make informed decisions and move on. The consistent implementation of these sets of conditions and outcomes is not easy; nevertheless, it is what is demanded from a nuclear regulatory agency in the 21st century: the application of safety margins using safety-engineering value judgments, aided by risk analysis methods. However, I believe that it is essential for an effective safety program to apply safety margins in a thoughtful and consistent manner. When engineering margins are applied to input parameters, they can distort our understanding of what is truly important. Safety margins are better discerned when they are applied at the decision-making stage rather than at the analysis stage of an issue. The overall effect of the safety margin is better understood and more meaningful when done in this manner.

Safety Management

Now let me turn my attention to Safety Management. Safety Management refers to the integration of three interrelated elements:

First, a functional and executable commitment to operational, maintenance and engineering safety, imbedded in every activity of the organization,

Second, the technical expertise that is applied where and when it should be; able to receive, process, form and communicate technical issues, cognizant of safety functions and safety systems, with licensing and regulation as boundary conditions but taken beyond them by the pursuit of safety and reliability.

Third, the people, programs, and processes to implement a safety program effectively.

Simply stated, safety management involves commitment to safety, the technical expertise to understand what is important, and good management to put the commitment and expertise into action. These elements taken together achieve the requisite adequate protection we demand and the reliability the nuclear industry needs.

I recognize that safety management is not easy; and that they are difficult and complex situations, issues and decisions that both regulators and licensees need to face. But I also recognize that these difficulties are manageable when we have a clear understanding of what is important and what is not; and when we have policies, programs and practices which recognize and appropriately address what is important and what is not; and when we have talent, training, and tools to help us implement these concepts. The NRC supports a regulatory approach in which safety management is implemented through commitment, competence, and the appropriate application of resources - Commitment to doing the right things - knowing "what the right things" are, and the capability to "reduce them to practice" through the application of appropriate resources.

Summary

A key, real and present crisis of our times was clearly portrayed by George Gilder when he stated:

> "It was [is] the survival of unprecedented multitudes of human beings at ever increasing standards of living, together with a new intolerance toward the persistence of conditions of poverty that had previously been accepted as inevitable."

In many ways, this succinct yet poignant statement expresses a fundamental social, political and economical issue confronting mankind, because it is a root cause of many of today's great problems,

and it has to be addressed with urgency and with solutions. And strongly tied with economic development, quality of life, health and safety is the global issue of environmental protection.

I happen to believe that energy, well distributed and affordable, is one of the key solutions to the existing crisis. And, I also believe that nuclear energy, safely deployed, can be part of the solution. Yet, for nuclear power to occupy its rightful place in the energy portfolio of the world, much work is still needed. This work is a shared responsibility.

Every nuclear operator needs to be committed to safety first and foremost; only through effective safety management can reliability and productivity be achieved. Every nuclear regulator is given a mandate to enable the beneficial uses of nuclear energy and radiation, and entrusted with the responsibility of assuring protection of the public and the environment. We know that the mandate and the responsibility are compatible and doable.

With this in mind, I am convinced that 21st century nuclear regulation needs to be driven by a thoroughly integrated set of safety concepts, a seamless fabric, a construct which includes risk-informed and performance-based regulation; which treats reactor safety, physical security and emergency preparedness in a holistic manner; which employs realistic conservatism in analysis and employs safety management in operational decisions. I see this regulatory construct as a fundamental, enabling factor for the safety and reliability of the existing and future nuclear power plants. And it not only has to be done well, it has to be communicated to decision-makers and the public very well!

The U.S. Nuclear Regulatory Commission is committed to fulfill its mandate and discharge its responsibility in a manner that fits the changing needs of our people and for their common good.

I want to thank you for the opportunity to share my views with you and wish you a successful conference, safety and reliability.